inventive concept and refers to U.S. Publication No. 2002/0182268 (Bessette, et al.) for the teaching of the technical feature of a topically transdermal patch comprising cellulose-based substances (i.e., hydrophilic polymer), polyacrylates (i.e., adhesive polymer), cyclodextrins (i.e., adsorbent) and essential oil, and states that there is no special technical feature in the application. In particular, the Examiner states that the inventions of Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. Consequently, the Examiner concludes that the groups are not so linked as to form a single general concept under PCT Rule 13.1, and therefore the claims lack unity of invention.

The Examiner also concludes that the present application contains claims which are directed to more than one species of the generic invention and therefore these species lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner considers the species of this application to be the many different hydrophile polymers in claim 3, the many different adsorbents in claim 4, the many different emulsifying agents in claim 5, the many different essential oils in claim 7, the many different adhesive polymers in claim 10, the many different cellulose derivatives in claim 27 and the many different gums in claim 27. The Examiner is requiring that the Applicant elect a single species in each of claims 3, 4, 5, 7, 10 and 27 to which the claims shall be restricted.

The Applicants hereby elect the claims of Group I (which reads on claims 1-12 and 25-33) for further prosecution on the merits thereof. However, the Applicants respectfully object to the instant restriction requirement, with traverse, as discussed

below.

The present application pertains to a medicinal skin patch, rather than a transdermal therapeutic system (TTS), for the treatment of colds by releasing essential oils through evaporation (emphasis added) (see, for example, claim 1). The skin patch comprises a backing layer which is permeable to gas and water vapor, a hydrophile and a pressure sensitive polymer matrix connected to the backing layer. The matrix comprises at least one essential oil, at least one hydrophile polymer at least one substance having an absorbent effect and/or at least one substance having an emulsifying effect, as well as at least one pressure sensitive polymer.

The medicinal patches of the present invention adhere to the skin of an ill person, such as in the chest region. In this way, the active substance (i.e., the essential oils) are continuously released by evaporation through the permeable backing and inhaled by the person via the nose or mouth, thereby providing a soothing and antibacterial effect on the respiratory tract. Moreover, it is submitted that the process for producing the skin patches of the present invention is improved by prolonged pot life due to the addition of absorbing substances.

The aforementioned Bessette, et al. reference, which is presumed to teach all special technical features of the skin patch of the present invention, is directed to pharmaceutical compositions containing essential oils for the prevention and treatment of cancer. As a suitable pharmaceutical administration form, which is considered to be rare for the application of the active compound to the skin, i.e., suspended or dissolved in a carrier, topical transdermal (emphasis added) patches are listed.

However, these patches significantly differ in design and composition from those according to the present invention. As set forth in Bessette, et al., the active compound is topically applied to the skin. To accomplish this feature in a transdermal patch, the backing of the patch has to be impermeable to gas and water, or at least to the active substance, to avoid loss of substance by evaporation or diffusion and to maintain a high concentration of active substance in the matrix in order to provide sufficient flux through the skin. This is important as the active substance is a volatile compound, such as an essential oil as in the case of Bessette, et al. Moreover, in general, penetration enhancers have to be applied to enable absorption of the active substance through the skin and the matrix has to be carefully designed not to bind the active substance or to impede its movement to the skin surface.

As to the application of the active substance to and via the respiratory tract, Bessette, et al. suggest nasal aerosols or inhalation (see, for example, paragraph [0025]) of compositions which are prepared according to well known techniques, such as in saline or the like (see, for example, paragraph [0026]). However, application as a medicinal patch is not suggested.

In contrast, the medicinal patches of the present invention provide a method for treating by the continuous inhalation of active substances which are evaporated through the permeable backing of the patch. Thus, topical application to the skin and the corresponding well known problems to generate and maintain a sufficient flux of the active substance through the skin are avoided and overcome by the medicinal patches of the present invention which make use of the volatility of the active substances.

Therefore, due to the aforementioned differences, the medicinal patches of the present invention having a permeable backing for the active substance are neither described nor suggested in the cited Bessette, et al. reference. It is submitted that the same holds true for the production process with improved pot life of the matrix polymer composition. In turn, Bessette, et al. does not disclose all the special features of the medicinal patches of the present invention and it is therefore respectfully submitted that the claims of Groups I-III are linked by a single inventive concept according to PCT Rule 13.1.

The Applicants respectfully request that the Examiner's restriction requirement be reconsidered in favor of unity of invention. However, the Applicants further wish to elect the species provided in the "1st Recipe" (paragraph [000046]), as noted below:

[000046] 1st Recipe Example:

- 36.2% by weight of DUROTAK® 387-2054 (polyacrylate pressure-sensitive adhesive; National Starch and Chemical Co.),
- 0.5% by weight of Al-acetylacetonate (crosslinking agent),
- 36.7% by weight of karaya gum,
- 6.9% by weight of TWEEN 80,
- 6.9% by weight of ATMOS® 300 (antifoaming agent),
- 6.2% by weight of camphor,
- 2.9% by weight of menthol,
- 3.7% by weight of pine oil.

The Applicants also respectfully traverse the second restriction requirement. It is submitted that the object of the present invention is to provide a medicinal patch for evaporating a constant amount of essential oils for an extended period of time. In

contrast to the teachings of Bessette, et al., which are directed to the topical application through the skin, the requirements for the properties of the matrix are lower since skin permeation and diffusion of the active substance are irrelevant for patches according to the present invention. Therefore, as long as each component of claims 3, 4, 5, 7, 10 and 27 is present in the matrix of the patch according to the present invention, the alternative single species are linked by the same inventive concept, i.e., the active substance evaporating patch.

The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: August 6, 2007

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